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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/10/2006

Masahiro Yamauchi

2006\_1488A

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513 7590 12/30/2010  
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EXAMINER

EPSS -SMITH, JANET L

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

12/30/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### **DETAILED ACTION**

1. Claims 1-38, 41, 43-47 and 49 were cancelled by Applicants. Claims 39-40, 42, 48, and 50 are pending for examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 103***

3. Claims 39-40, 42, 48 and 50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kato et al. (US20040022938).
4. Applicant's arguments filed 12/10/2010 have been fully considered but they are not persuasive. Applicants traversed the rejection of the instant claims over Kato et al. on the grounds that Kato does not expressly teach the combination of a nucleic acid and an anionic polymer with liposome. On this basis, Applicants concluded that the "combination of nucleic acid, liposome and anionic polymer in the claimed invention are different from the teachings of Kato et al. and the selection of plasmid or siRNA is over a design choice."
5. Contrary to Applicant's assertions, the instant rejection is not one of anticipation as asserted by Applicants on page 2 of the reply filed 12/10/2010. Although Applicants focus upon the explicit examples of Kato et al. the instant rejection is based upon what would have been obvious to the ordinary skilled artisan at the time the instant invention was made.

Art Unit: 1633

6. Despite Applicant's assertion that Kato et al. does not explicitly disclose a nucleic acid combination with a liposome and dextran sulfate, Kato et al. clearly teaches a method for coating fine particles with lipid membrane, wherein the fine particles comprise a complex of a drug, liposome containing phospholipid and a dextran sulfate sodium salt, (¶ [0020]). Kato et al. further teaches wherein the drug is a nucleic acid, and further wherein said nucleic acid is a gene (see ¶ [0030]), antisense oligonucleotide, sense oligonucleotide, DNA and RNA.

7. Although Kato et al. does not expressly describe a complex of plasmid or siRNA, liposome and anionic polymer, absent evidence to the contrary, it would have been obvious to substitute alternative, structurally equivalent forms of nucleic acid, such as plasmid or siRNA for the forms of nucleic acid used in the complexes of Kato et al. It is clear that the novelty of the claimed invention is not associated with the class of nucleic acid, as evidenced by ¶ [0018] of the specification as filed, which recites: "[T]he method of inhibiting aggregation of complex particles according to the above (8), wherein the nucleic acid as the drug is one or more substance(s) selected from genes, DNA, RNA, oligonucleotides, plasmids and siRNA." Therefore, the selection of plasmid or siRNA as the nucleic acid in the complexes of the claimed invention is simply a matter of design choice.

8. Additionally, in regards to the increase in efficiency observed due to the presence of anionic polymer in Examples 15-17 of the specification as filed, Applicants have not provided any evidence that this observation is unexpected in light of the teachings of

Art Unit: 1633

Kato et al. The arguments of counsel cannot take place of evidence of non-obviousness, see MPEP § 2145.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/  
Primary Examiner, Art Unit 1633